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| 10/575,962  | 01/19/2007  | Ekkehard Werner      | 097147-0108         | 5655             |
| 23428 7590 03/17/2011<br>FOLEY AND LARDNER LLP<br>SUITE 500<br>3000 K STREET NW<br>WASHINGTON, DC 20007 |             |                      |                     |                  |
| EXAMINER  |             |                      |                     |                  |
| CHUNDURU, SURYAPRABHA   |             |                      |                     |                  |
| ART UNIT  |             | PAPER NUMBER         |                     |                  |
| 1637  |             |                      |                     |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/575,962

**Applicant(s)**

WERNER, EKKEHARD

**Examiner**

Suryaprabha Chunduru

**Art Unit**

1637

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 May 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 27-45 is/are pending in the application.
- 4a) Of the above claim(s) 36-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27-35 and 39-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-945)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 5/31/06; 4/23/09
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. Applicant's election with traverse of Group I (claims 27-35, 39-45) in the reply filed on December 29, 2010 is acknowledged. The traversal is on the ground(s) that examining both the groups together would not be a search burden since search for one group would result in art for another group. The arguments are found unpersuasive because of the following reasons: (i) a search for one group does not necessarily result in an art related to another group (ii) this application is a 371 case and for applications filed under 371, PCT rules for lack of unity apply (iii) search burden is not required to show lack of unity. (iv) Further, the X category reference indicates a lack of special technical feature, which supports that each of the groups of invention do not relate to a single inventive concept. Thus the lack of unity is deemed proper.

**Status**

2. Claims 27-35 and 39-45 are considered for examination. Claims 36-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group.

**Priority**

3. This application filed on January 19, 2007 is a 371 of PCT/EP04/11564 filed on 10/14/2004 which claims foreign priority to EPO 0302352.1 filed on 10/15/03.

**Information Disclosure Statement**

4. The Information Disclosure Statement filed on May 31, 2006 and April 23, 2009 have been considered and acknowledged.

**Informalities**

5. The following informalities are noted:

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- (i) claim 42 do not end with a period (.) or a full stop.
- (ii) the preamble of claim 42, line 4 ends with a full stop or a period (.) making incomplete sentence.
- (iii) claims 27, 44-45 recite (a.1) and (a.2). Amending the sub-steps by using (i) and (ii) is suggested.

### **Claim Rejections - 35 USC § 112**

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A. Claim 34 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The meets and bounds of the claim 34 are indefinite and unclear because claim 34 is dependent on cancelled claim 1 and it is not clear what limitations of cancelled claim 1 are required for the instant claim.

B. Claims 42-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 42 recites the limitation "the target" in line 2 of step (a). There is insufficient antecedent basis for this limitation in the claim because target region do not have support in the preceding lines of the method. The meets and the bounds of the claims are unclear and indefinite because step a) line one recites nucleic acid targets (plurality) and the following limitations recite a single region of a microorganism. Further it is unclear whether the recitation of 'a microorganism in step a)

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represents the same microorganism recited in the preamble of the claim or does it represent a different microorganism.

C. Claims 27-35, 39-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 27, steps (a) – (d) recite the limitation a microorganism. The meets and bounds of the claims are unclear and indefinite because it is unclear whether the recitation of ‘a microorganism in step a) represents the same microorganism recited in the preamble of the claim or does it represent a different microorganism.

#### **Claim Rejections - 35 USC § 102**

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

A. Claims 42-43 are rejected under 35 U.S.C. 102(e) as being anticipated by Happe et al. (US2005/0064451 A1).

Happe et al. teach a method of claim 42, detecting a microorganism contamination in a culture of eukaryotic cells to be used for gene expression profiling, or

for analyzing the effect of microorganism contamination on the gene expression of eukaryotic cells or for gene expression profiling by detecting the presence or absence of a microorganism comprising preparing nucleic acid targets by use of a primer comprising the nucleic acid sequence complementary to the target region of a microorganism (see page 14, paragraph 0165, page 15, paragraph 0166).

With regard to claim 43, Happe et al. teach that the target region of said microorganism is 16S rRNA and the microorganism is Mycoplasma (see page 14, paragraph 0165, page 15, paragraph 0166). Accordingly the claims are anticipated.

A. Claims 27-28, 39-42, 44-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Lockhart et al. (US 6,548,257).

Lockhart et al. teach a method of claim 27, of detecting a microorganism in a culture of eukaryotic cells comprising providing

(a) a microarray which comprises at least one nucleic acid probe representing a gene for eukaryotic cell and at least one nucleic acid probe representing a gene (Bio B gene) of a microorganism (see col. 17, line 35-63, col. 25, line 50-67, col. 26, line 1-67, col. 27, line 1-23, table 1);

(b) preparing nucleic acid targets from said culture by means of a primer mixture suitable for amplification of said gene from eukaryotic cell and at least one gene from a microorganism (see col. 11, line 1-19, col. 12, line 59-67);

(c) contacting the microarray with the nucleic acid targets (see col. 27, line 24-34);

(d) and detecting the hybridization signals there by detecting a microorganism and detecting expression of genes specific for the eukaryotic cell (see col. 28, line 4-43).

With regard to claim 28, 39-41, Lockhart et al. teach comparing the gene expression of eukaryotic cells with the gene expression of non-contaminated eukaryotic cells (see col. 28, line 4-67, col. 29, line 1-35).

With regard to claim 42, Lockhart et al. teach detecting a microorganism contamination in a culture of eukaryotic cells to be used for gene expression profiling, or for analyzing the effect of microorganism contamination on the gene expression of eukaryotic cells or for gene expression profiling by detecting the presence or absence of a microorganism comprising preparing nucleic acid targets by use of a primer comprising the nucleic acid sequence complementary to the target region of a microorganism (see col. 11, line 1-19, col. 12, line 59-67).

With regard to claim 44-45, Lockhart et al. teach that the gene expression profiling is done by using a microarray which comprises at least one nucleic acid probe representing a gene for eukaryotic cell and at least one nucleic acid probe representing a gene of a microorganism (see col. 17, line 35-63, col. 25, line 50-67, col. 26, line 1-67, col. 27, line 1-23, table 1).

### **Claim Rejections - 35 USC § 103**

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 29-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Happe et al. (US 2005/0064451A1) in view of Lockhart (US 6,548,257).

Happe et al. teach a method for detecting a microorganism contamination in eukaryotic cells as discussed above in section 7A. Happe et al. also teach that the microorganism is selected from mollicutes (mycoplasma) and the nucleic acid probe comprises 16S rRNA gene of mycoplasma comprising the sequence of SEQ ID No. 1, 3, 4 or 5 and primers for preparing the target nucleic acid comprises promoter sequence as defined in SEQ ID No. 2 and eukaryotic cells comprise human cells (see page 14, paragraph 0165, page 15, paragraph 0166, page 21, claims 57-62).

However Happe et al. did not specifically teach detecting the target nucleic acids by using a microarray comprising probes specific for at least one gene of eukaryotic organism and at least one from a microorganism.

Lockhart et al. teach that the gene expression profiling is done by using a microarray which comprises at least one nucleic acid probe representing a gene for eukaryotic cell and at least one nucleic acid probe representing a gene of a microorganism (see col. 17, line 35-63, col. 25, line 50-67, col. 26, line 1-67, col. 27, line 1-23, table 1).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to modify the method for detecting a microorganism as taught by Happe et al. with the use of a microarray as taught by Lockhart et al. for the purpose of developing a simple and efficient method for detecting a microorganism contamination of a culture of eukaryotic cells. One skilled in the art would have motivated to combine the references because the ordinary artisan would have a

reasonable expectation of success that the combination would result in a simple, efficient method for simultaneously detecting multiple target nucleic acids in a high throughput format (see col. 2, line 54-61) and such a modification of the method would be obvious over the cited prior art.

### **Conclusion**

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Suryaprabha Chunduru/

Primary Examiner, Art Unit 1637

